

Application Serial No.: 09/884,478

Attorney Docker No.: 64118.000010

REMARKS

Claims 1-48 are pending in the application. By this Amendment, claims 2, 8, 9, 39, 40 and 41 are amended to further distinguish the claimed invention.

No new matter has been added by this amendment. Support for the amendments to claims 8 and 9, for example, may be found in Fig. 3 and paragraphs 90-91, for example.

Applicant notes the objection to claim 47 is withdrawn.

A. The Rejection Based on Joao and Soll

In the Office Action, claims 1-13, 15-19, 25-39, and 41-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Joao, (U.S. Pub. 2001/0032099) in view of Soll et al., (U.S. Pub. 2003/0055679). This rejection is traversed.

In the present Office Action, the Examiner has maintained the rejection based on Joao and Soll. Various aspects of such rejection are discussed in Applicant's prior August 7, 2006 Amendment. In the present Office Action, further comments are provided as to the manner in which the applied art allegedly teaches the claimed invention.

That is, on pages 3-4, the Office Action asserts that Soll teaches:

... both (1) the at least one pre-event set of electronically displayable files containing health information for preparing and educating the patient for the medical event and (2) the at least one post-event set of electronically displayable files are pre-determined such that the files are stored in the healthcare information provider system in anticipation of the event and prior to the event, and such that the files are related so as to provide a treatment pathway, (Soll, paragraphs 64, 65) (disclosing pre-event files for priming a patient, and post-event files for exit interviews, both of which are related so as to provide a treatment pathway).

The Office Action further asserts that Joao discloses an electronic patient healthcare

Application Serial No.: 09/884,478

Attorney Docket No.: 64118.000010

system comprising a storage device and a patient terminal device, with input and display capabilities, for storing and processing patient and doctor information; and that Joao fails to disclose a system for guiding a patient along a treatment pathway, related to a medical event, by educating and preparing the patient for the medical event and post-event recovery. The Office Action proposes to cure the deficiencies of Joao with Soll. That is, the Office Action asserts that however, the claimed system is well known in the art as shown above by reference to Soil.

The Office Action concludes that it would be obvious to one of ordinary skill in the art to combine Joao and Soll; and that the motivation would be to improve health care delivery to patients and better manage the process of providing health care, such system also providing high-quality health care at lower costs, (Soll, Abstract).

Applicant respectfully traverses the rejection as the Action fails to establish a *prima facie* case of obviousness to reject claim 1. In order to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. See M.P.E.P. § 2143.

For at least the following two reasons, the Action does not establish a *prima facie* case of obviousness to reject claim 1 based on the applied art to Joao and Soll.

The above selected portions of the Office Action allegedly support an assertion that the applied art teaches the features set forth in the last clause of claim 1. Therein, claim 1

Application Serial No.: 09/884,478

Attorney Docker No.: 64118.000010

recites:

both (1) the at least one pre-event set of electronically displayable files containing health information for preparing and educating the patient for the medical event and (2) the at least one post-event set of electronically displayable files are **predetermined** such that the files are stored in the healthcare information provider system in anticipation of the event and prior to the event, and such that the files are **related** so as to provide the treatment pathway.

The teachings of Joao and Soll, either alone or collectively, fail to teach the claimed invention as recited in claim 1. The Office Action acknowledges that Joao fails to disclose a system for guiding a patient along a treatment pathway, related to a medical event, by educating and preparing the patient for the medical event and post-event recovery, but that however, such a system is well known in the art as shown above by reference to Soll. Applicant submits that Soll fails to cure the deficiencies of Joao so as to teach or suggest the invention of claim 1.

In contrast to the claimed invention, in paragraphs 64 and 65 as referenced in the Office Action, Soll teaches incorporating patient-centered care into routine practice. Soll teaches a computerized strategy, implemented at both the patient and physician modules facilitates patient-centered care. This strategy includes a variety of functions, such as enhancing physician-patient communication; educating and activating (priming) patients to provide an accurate history; clarifying and transmitting patient's health questions and illness concerns to the physician; assessing the patient's health attitudes; and collecting comprehensive biopsychosocial data. Soll teaches the psychosocial screening assessment examines several domains, including physical symptoms that may represent somatization,

Application Serial No.: 09/884,478

Attorney Docket No.: 64118.000010

life events that are perceived as stressful (e.g., relation, financial, and work-related stress) and psychologic co-morbidity (e.g., depression or anxiety states).

In paragraph [0065], Soll further teaches that several mechanisms serve to increase the likelihood that the physician attends to patient-centered care issues. At exit and revisit interviews, the various aspects of patient-centered care are evaluated and related to data on physician process. Issues relating to patient-centered care, such as psychosocial factors, health attitudes, illness concerns and questions, are presented to the physician as provisional problems. These patient-centered aspects of care are implemented in anticipation that they are important determinants of the response to therapy and overall outcomes.

However, as was discussed in the August 7, 2006 Amendment, such teachings fail to teach or suggest what might be characterized as the continuum reflected in the claimed invention, revolving around a medical event, i.e., before and after a medical event. In particular, such teachings fail to teach or suggest both (1) the at least one pre-event set of electronically displayable files containing health information for preparing and educating the patient for the medical event and (2) the at least one post-event set of electronically displayable files are **predetermined** such that the files are stored in the healthcare information provider system in anticipation of the event and prior to the event, and such that the files are **related** so as to provide the treatment pathway.

Further, the other teachings of Soll, which allegedly cure the deficiencies of Joao, fail to teach the claimed invention, either alone or together with Joao. For example, in paragraph 97, Soll teaches an interactive module that includes educational sequences and evaluation questions developed for collecting informed consent of patients. Applications include informed consent for routine procedures or surgery as well as for clinical investigation to

Application Serial No.: 09/884,478

Attorney Docket No.: 64118.000010

meet Institutional Review Board requirements for human subjects. To improve patient comprehension, this module incorporates video clips and audio and visual aids so that appropriate information is conveyed to the patient regarding the intervention they will receive. Because the information presented can be catered to patient characteristics, appeals to a variety of learning styles with its multimedia format, and can be reviewed or repeated at the patient's pace, this sequence provides an effective means for education on informed consent issues. Evaluation questions and internal system checks (described above) assess the patient's level of understanding of the material presented.

However, such disclosure also fails to teach or suggest the claimed invention. Rather, such teachings relate to informed consent, prior to a medical procedure.

Further, Applicant notes Soll's disclosure in paragraph [0174-0181]. Soll teaches patients are given personalized instructions and education material "when they leave the clinic." Soll teaches the physician selects this material for the patient from a menu of prepared text and graphics, block 1360: a health summary prepared for the patient based upon the identified problems and symptoms; instructions for diagnostic studies, procedures, treatment plans; instructions for self-care and lifestyle measures; the agenda for future visits and consultations; and educational materials for identified problems. Soll describes the physician then reviews, edits and authorizes the final clinical report and execution of management orders (blocks 1370 and 1380).

However, such disclosure of Soll is directed to information provided to the patient after the visit. In particular, Soll fails to teach claimed files that are related so as to provide the treatment pathway, and the at least one pre-event set of electronically displayable files containing health information for preparing and educating the patient for the medical event,

Application Serial No.: 09/884,478

Attorney Docket No.: 64118.000010

and at least one post-event set of electronically displayable files for post-event recovery, in conjunction with the features that both such sets of files are **predetermined** such that the files are stored in the healthcare information provider system **in anticipation of the event** and prior to the event, and such that the files are **related** so as to provide the treatment pathway.

Applicant submits that Soll in particular fails to teach that the files are "predetermined" and the manner in which the files are "related". Further, such claimed features, as recited in claim 1, relate to "a" medical event, i.e., a single event. Soll fails to teach the interrelationship of the claimed features to a single event.

Applicant submits that the collective features of the claimed invention clearly reflect a "treatment pathway" relating to an "event". Soll simply does not teach a treatment pathway with the various particulars as recited in claim 1. For example, in paragraph 58, Soll describes:

Patient exit and revisit interviews assess response to treatment process. During clinic visits, patients initially undergo the computerized CPM interview session and are then evaluated by a physician. Finally, the patient returns to the patient cart for an exit interview, to receive a personalized health summary, instructions for self-care and follow-up, and educational materials. The patient's response to the physician encounter is sought, focused on the effectiveness of communication and understanding of the physician's diagnosis and plans for testing and treatment. When the patient returns to clinic, CPM operates in a revisit mode, reconstructing prior symptoms and problems, assessing compliance with medications or other recommendations, eliciting patient response to therapy and other changes in symptoms, quality of life or health status, and collecting patient questions and concerns. These exit and revisit sessions provide a unique opportunity to further understand the natural history of common medical problems and assess the patient's response to physician process, specific treatments, or overall management strategy.

However, such teachings also fail to set forth the claimed "treatment pathway" related to a

Application Serial No.: 09/884,478

Attorney Docket No.: 64118.000010

medical event, as is specifically set out, in detail, in claim 1. For example, as noted above in paragraph 0058, Soll talks that the patient "returns to the patient cart for an exit interview, to receive a personalized health summary, instructions for self-care and follow-up, and educational materials." However, Soll fails to make any assertion as to the "predetermined" nature of the files or the interrelationship of the files (with other files) so as to teach claim 1. Rather, Soll merely asserts that such files are presented to the patient. The is, the claimed interrelationship between such files and other files is simply not present.

For at least the reasons set forth above, Applicant submits that the applied art to Joao and Soll fails to teach or suggest the claimed features as recited in claim 1. Further, claims 8, 13, 19, 25, 30 and 39 define patentable subject matter for reasons similar to those set forth above with respect to claim 1.

Further, the various dependent claims define patentable subject matter for at least the reasons set forth with regard to the corresponding independent claims, as well as for the additional features such dependent claims recite.

The Rejection of Claim 5

In particular, Applicant submits that the rejection of claim 5, as set forth in the Office Action, is deficient. Claim 5 recites:

The system of claim 1, wherein at least one of the pre-event and post-event sets of files includes a calendar file that displays a schedule of time specific events associated with the treatment pathway, said calendar file adapted to be modified by the patient using the input device of the patient terminal device.

The Office Action addresses such claim on page 6 (paragraph 7). In particular, the Office Action asserts that Joao discloses "a system wherein at least one of the pre-event and post-

Application Serial No.: 09/884,478

Attorney Docket No.: 64118.000010

event sets of files includes a calendar file that displays a schedule of time specific events associated with **the treatment pathway**". However, in the rejection of claim 1 (Office Action page 4, lines 7-10), the Office Action asserts that **Joao fails to teach the claimed treatment pathway**.

Accordingly, Applicant submits that the rejection is unsupportable, in that the rejection asserts that Joao teaches the calendar file associated with the treatment pathway hand-in-hand with the Office Action acknowledging that Joao does not teach the treatment pathway in and of itself. Accordingly, such rejection clearly cannot be supportable.

The Rejection of Claim 2

Further, Applicant traverses the rejection of claim 2 in particular. As to claim 2, the Office Action asserts in paragraph 4:

However, Soli further discloses a system wherein said electronically displayable files include a single electronically displayable file including a treatment pathway timeline display, comprising a plurality of time-sequenced phase images corresponding to time-sequenced phases of health information thereby illustrating the treatment pathway (Soli, Abstract, paragraphs 64, 65, 97, 156-159, 174-183) (The dynamic, problem-oriented CPM record to be accessed under each problem heading by date is considered to be analogous to a treatment pathway timeline display comprising a plurality of time-sequenced phase images corresponding to time-sequenced phases of health information).

While various portions of Soli are referenced, Applicant notes in particular Soli at paragraph 0157. Therein, Soli describes such dynamic, problem-oriented CPM record. Soli reaches:

The invention makes data more accessible, allowing all information on a given problem to be readily found and retrieved. Information is organized and accessible by problem; the data for **each problem are organized by date under the headings indicated in Table 5**. A summary category is also available to capture an overview of the problem. The physician module allows filters to be applied to the data so that only the problem name and most recent entries are displayed. Alternatively, the physician can display data by other filters (e.g., all data, data by author, or another sub-

Application Serial No.: 09/884,478

Attorney Docket No.: 64118.000010

category).

However, such teachings of Soll fail to teach the totality of the claimed invention as recited in claim 2. Soll fails to teach the claimed association between the "treatment pathway timeline display" and the treatment pathway, in conjunction with the various attributes of the treatment pathway set forth in claim 1. Claim 2 has further been amended to more clearly recite the claimed invention. Thus, even if Joao were somehow modified by Soll, the collective applied art would fail to teach the claimed invention, and the various particulars thereof.

Further, such asserted teachings of Soll's paragraph 0157 go to physician interaction. In contrast, the claimed invention clearly relates to patient interaction, as the Office Action appears to reflect on page 5, lines 18-20 (and the rejection of claim 3). However, by such proposed analysis, the Office Action proposes to **first modify** Joao by Soll's alleged teaching of electronic links between the time sequenced phase images and the pre-event/post event set of files. Thereafter, the Office Action proposes to **yet further** modify Soll's teaching (which was used to modify Joao). Such analysis (constituting a modification of a modification) clearly extends beyond what would have been obvious to the one of ordinary skill in the art, and sounds strongly of inappropriate hindsight analysis.

Applicant submits that the claims define patentable subject matter. Withdrawal of the rejections are respectfully requested.

D. The 35 U.S.C. §103 rejection based on Joao and Soll, and Schoenburg

In the Office Action, claims 14, 20-24, 40, 47, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over the collective system of Joao and Soll as applied to claims 13, 19, and 39 above, and further in view of Schoenburg et al., (U.S. 6,463,417). This

Application Serial No.: 09/884,478

Attorney Docket No.: 64118.000010

rejection is traversed.

For example, the Office Action asserts, as per claim 14, the collective system of Joao and Soll disclose the method of claim 13, but that however Joao and Soll fail to clearly disclose a method further including the steps of providing the patient with a medical practitioner code designating the medical practitioner conducting the medical event and requiring the patient to input the medical practitioner code into an electronically displayable file containing a code input field and transmitting the code to the healthcare information provider system.

The Office Action attempts to cure the asserted deficiencies with the teachings of Schoenburg. In particular, the Office Action asserts that Schoenburg discloses a method including the steps of providing the patient with a medical practitioner code designating the medical practitioner conducting the medical event and requiring the patient to input the medical practitioner code into an electronically displayable file containing a code input field and transmitting the code to the healthcare information provider system, the Office Action referencing Schoenburg, Abstract, Fig. 2, Col. 3, lines 20-52; Col. 4, line 52 through Col. 5, line 40). The Office Action concludes it would be obvious to one of ordinary skill in the art to combine Schoenburg into the collective system of Joao and Soll, and that the motivation would be to provide a method of and system for distributing medical information in which the medical provider has quick access to a patient's medical record, but only to the information in the medical record that is necessary for the proper treatment of the patient at that time, (Schoenburg, Col. 2, lines 16-22).

As to this and the other asserted proposed modifications of Joao based on Soll and Schoenburg, Applicant submits that even if it were obvious to so modify Joao, which it is not

Application Serial No.: 09/884,478

Attorney Docket No.: 64118,000010

so admitted, such modification would still fail to cure the deficiencies of Joao, so as to teach the claimed invention as recited in the respective independent claims.

For at least the reasons set forth above, Applicant submits that the applied art to Joao, Soll and Schoenburg fails to teach or suggest the claimed features. Withdrawal of the 35 U.S.C. §103 rejections are respectfully requested.

E. Conclusion

Should the Examiner believe anything further is desirable in order to examine the application or place the application in better condition for allowance, the Examiner is invited to contact Applicant's undersigned representative at the telephone number listed below.

For any fees due in connection with filing this Response the Commissioner is hereby authorized to charge the undersigned's Deposit Account No. 50-0206.

Respectfully submitted,
HUNTON & WILLIAMS



James R. Miner
Registration No. 40,444

Hunton & Williams
1900 K Street, N.W., Suite 1200
Washington, D.C. 20006-1109
(202) 955-1500

Dated: February 20, 2007